



DEPARTMENT OF HEALTH & HUMAN SERVICES

M1030 N

Public Health Service

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-97-67

June 26, 1997

Ken Smith, Technical Director
The Imaging Center of Orlando
1809 Bellevue Avenue
Orlando, Florida 32806-2905

Dear Mr. Smith:

Your facility was inspected on April 9, 1997 by a representative of the State of Florida, State Department of Health and Rehabilitative Services, Bureau of Radiation Control, under contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

- Interpreting physicians, [REDACTED] and [REDACTED], are unqualified to interpret mammograms due to the lack of a state license to practice medicine.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These level 2 noncompliances include:

- The measured darkroom fog exceeded 0.05 (the measured fog level was 0.11)

- Interpreting physicians, [REDACTED], [REDACTED], and [REDACTED], do not meet the continuing experience requirement, i.e., interpreting an average of 40 patient examinations per month over 24 months.

- Interpreting physicians, [REDACTED] and [REDACTED], do not have the initial training of 40 hours of continuing medical education in mammography.

Mr. Ken Smith
Page 2
June 26, 1997

- Interpreting physician's, [REDACTED], [REDACTED], [REDACTED], and [REDACTED], initial experience are inadequate (reading and interpreting mammograms from the examination of at least 240 patients in 6 months).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 and regulations under the Act. The specific deficiencies noted in the letter and in the printed summary of test results listed under the Level 1 heading on your MQSA Facility Inspection Report, issued at the close of the inspection, may be symptomatic of serious underlying problems in your facility's quality assurance program for mammography.

You should take prompt action to correct these violations. Failure to promptly correct this violation may result in regulatory action being initiated by the Food and Drug Administration without further notice. A facility may be subject to civil money penalties up to \$10,000 for each failure to substantially comply with, or each day on which a facility fails to substantially comply with the Standards. A facility may also have its certificate suspended or revoked for failure to comply with the Standards. Continuation or any activity related to the provision of mammography by a facility that constitutes a serious risk to human health may result in injunction.

You should be advised that FDA regulations do not preclude enforcement of requirements under State laws and regulations. In some cases, State requirements may be more stringent than requirements under FDA regulation. You may receive a letter or notification from the State advising you of this fact. When conducting corrective actions, you should take into consideration the more stringent State requirements. A copy of your response to the FDA should always be sent to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be completed.

Mr. Ken Smith
Page 3
June 26, 1997

The original copy of your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809. Also send a copy to the Florida Department of Health, Bureau of Radiation Control, Radiation Machine Program, P.O. Box 210, Jacksonville, FL 32231.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Thomas R. Trout, FDA, Southeast Regional Radiologic Health Representative, at (404) 347-3576.

Sincerely yours,

A handwritten signature in dark ink, reading "Douglas D. Tolen". The signature is fluid and cursive, with the first name "Douglas" and last name "Tolen" clearly legible.

Douglas D. Tolen
Director, Florida District